MAR 8 2002

K014054
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510(k) Summary, Safety and Effectiveness

Submitter:	Edwards Lifesciences LLC One Edwards Way Irvine, California 92614 USA
Contact:	Jason Smith Phone: 949-250-2662 Fax: 949-250-3579
Device Trade Name:	Edwards Lifesciences Swan-Ganz Monitoring Catheter with Oligon™ material
Common Name:	Intravascular Diagnostic Catheter
Classification:	Class II (Reference 21 CFR 870.1200)
Predicate or Legally Marketed Device:	Swan-Ganz Monitoring Catheter Baxter Healthcare Vantex™ Central Venous Catheters with Oligon™ material
Date prepared:	December 7, 2001

Device Description:

The Edwards Lifesciences Swan-Ganz Monitoring Catheter with Oligon™ material is used to monitor right heart pressures, sample mixed venous blood, and infuse solutions. The catheters are composed of a dual lumen body tube. The distal lumen terminates at the tip and is used to monitor pulmonary artery and wedge pressures. The distal lumen may also be used to sample venous blood and infuse solutions. The second lumen is used only to inflate the latex balloon which can be found at the distal end of the catheter. The function of the balloon is to enable the catheter to float down the bloodstream into the pulmonary artery. The balloon is inflated with a 3 cc syringe, which is connected to the inflation valve at the inflation lumen hub. The device will be packaged in a tray sealed with a tyvek lid and sterilized using 100% ethylene oxide.

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Indications for Use:

The Edwards Lifesciences Swan-Ganz Monitoring Catheter with Oligon™ material is indicated for the assessment of a patient's hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring. Secondary indications are for sampling blood and infusing solutions.

Technology Comparison:

The Edwards Lifesciences Swan-Ganz Monitoring Catheter with Oligon™ material is technologically comparable to the predicate devices in construction and physical specifications. Furthermore, design, manufacturing, and sterilization procedures are representative of current industry practices.

Test Summary, *In-vitro:*

Functional testing was performed on the Edwards Lifesciences Swan-Ganz Monitoring Catheter with Oligon™ material to evaluate the integrity and performance of the device. Based upon the results of this testing, Edwards Lifesciences has determined that the Edwards Lifesciences Swan-Ganz Monitoring Catheter with Oligon™ material is safe and effective and is acceptable in design and construction for its intended use.

Test Summary, *In-vivo:*

Clinical testing was not performed on the subject device because the intended use and indications are the same as the predicate devices. Furthermore, the Edwards Lifesciences Swan-Ganz Monitoring Catheter with Oligon™ material exhibited comparable design characteristics to the predicate devices in the *in vitro* testing, thus clinical testing was not performed.

Test Summary, Biocompatibility:

Biocompatibility testing was performed on the Edwards Lifesciences Swan-Ganz Monitoring Catheter with Oligon™ material in accordance with the requirements specified in International Standards Organization (ISO) 10993-1-1994 Biological Evaluation of Medical Devices - Part 1: Guidance on Selection of Tests and the FDA General Program Memorandum No. G95-1. The Edwards Lifesciences Swan-Ganz Monitoring Catheter with Oligon™ material was found to be biocompatible and nontoxic and acceptable for its intended use.

Rationale for Substantial Equivalence Determination:

The battery of non-clinical tests discussed above demonstrates that the Edwards Lifesciences Swan-Ganz Monitoring Catheter with Oligon™ material exhibit comparable mechanical and functional characteristics to the predicate devices in addition to being biocompatible and chemically acceptable. Based upon those characteristics, the Edwards Lifesciences Swan-Ganz Monitoring Catheter with Oligon™ material is substantially equivalent to the predicate devices in safety and effectiveness in addition to being intended for the same uses.

12/7/01

Jason Smith — Date
Senior Regulatory Affairs Specialist
Edwards Lifesciences

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 8 2002

Mr. Jason Smith
Senior Regulatory Affairs Specialist
Edwards Lifesciences, LLC
One Edwards Way
Irvine, CA 92614-5686

Re: K014054
Swan-Ganz Monitoring Catheter with Oligon Material
Regulation Number: 870.1200
Regulation Name: Diagnostic intravascular catheter.
Regulatory Class: II (two)
Product Code: 74 DQO
Dated: December 7, 2001
Received: December 10, 2001

Dear Mr. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram Zuckerman, M.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K01 4054

Device Name: Edwards Lifesciences Swan-Ganz Monitoring Catheter with Oligon™ material

Indications For Use:

The Edwards Lifesciences Swan-Ganz Monitoring Catheter with Oligon™ material is indicated for the assessment of a patient's hemodynamic condition through direct intracardiac and pulmonary artery pressure monitoring. Secondary indications are for sampling blood and infusing solutions.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K014054